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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant	:	Hugh Sharkey and Gary S. Fanton	Art Unit	:	3739
			Examiner	:	David M. Shay
Serial No.	:	08/714,987			
Filed	:	September 17, 1996			
Title	:	METHOD AND APPARATUS FOR CONTROLLED CONTRACTION OF SOFT TISSUE			

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BRIEF ON APPEAL

Applicant herewith files this Brief on Appeal, thus perfecting the Notice of Appeal which was originally filed on March 17, 2004. The headings and sections required by 37 CFR 1.192 follow:

(1) Real Party in Interest

The application is currently assigned to Smith & Nephew, Inc., who is, hence, the real party-in-interest.

(2) Related Appeals and Interferences

There are no known related appeals or interferences.

(3) Status of Claims

Claims 48, 50, 53-55, and 74-94 are pending. Each of these claims are rejected and appealed.

(4) Status of Amendments

A Response after Final was filed on November 17, 2003. In a subsequent Advisory Action, dated December 17, 2003, the Patent Office indicated that the Response after Final had been considered and did not place the application in condition for allowance.

(5) Summary of Invention

The present apparatus as set forth in claim 74 relates to an energy delivery device including a sensor completely enclosed by the thermally conductive material. Figs. 6 and 9a, for example, show such an apparatus. As explained in lines 11-30 of page 17 to line 1 of page 18, the sensor is positioned within the thermally conductive material to detect a thermal energy from

a selected site and from an adjacent fluid medium. As explained in lines 2-4 and the last paragraph of page 12, the sensor produces a thermal feedback signal which represents a composite of the thermal energy detected from the selected site of the collagen containing tissue and from the adjacent fluid medium.

Advantages of positioning the sensor to detect thermal energy from the selected site and adjacent fluid medium are discussed, for example, at page 18, line 23 to page 21, line 10. One advantage of positioning the sensor to provide a signal which represents a composite of the thermal energy contents of the selected site as well as fluid medium which is adjacent to the selected site, i.e., not within the tissue of the selected site itself, is that cell necrosis or over contraction caused by a second application of energy is reduced. This is because the sensor provides a feedback signal indicating an elevated thermal energy content due to the thermal energy content in the fluid medium and in response the device deliveries a reduced amount of energy to the selected site.

As explained in the last paragraph of page 11, the energy delivery device is configured to deliver sufficient energy to the selected site to effect a contraction in at least a portion of collagen containing tissue at the selected site.

The energy delivery device includes circuitry, for example, a conductor attached to the sensor, such as shown in Fig. 6, for supplying the thermal feedback signal to a feedback control system for adjusting a level of energy delivered by the energy delivery device to at least the portion of the selected site of the collagen containing tissue.

As explained in lines 8-11 of page 14, another aspect of the present invention set forth in claim 82 relates to an apparatus in which a feedback control system is coupled to the sensor and configured to receive the thermal feedback signal and adjust a level of energy delivered by the energy delivery device to at least the portion of the selected site of the collagen containing tissue.

The present method as set forth in claim 89 relates to delivering energy by providing an energy delivery device including a distal portion having a thermally conductive material and a sensor completely enclosed by the thermally conductive material. Figs. 6 and 9a, for example, show such a device. As explained in lines 11-30 of page 17 to line 1 of page 18, the sensor is positioned within the thermally conductive material to detect a thermal energy from the selected site and from an adjacent fluid medium.

As explained in the last paragraph of page 11, the method includes delivering sufficient energy with the distal portion of the energy delivery device to a selected site to effect a contraction in at least a portion of collagen containing tissue at the selected site.

As explained in lines 2-4 and the last paragraph of page 12, the method includes producing a thermal feedback signal which represents a composite of the thermal energy detected from the selected site of the collagen containing tissue and from the adjacent fluid medium with the sensor.

As explained in lines 8-11 of page 14, the method includes adjusting a level of energy delivered by the energy delivery device to at least the portion of the selected site based on the thermal feedback signal.

(6) Issues

Are claims 48, 50, 53, 74, 75, 77-83, and 85-88 properly rejected under 35 U.S.C. §102(b) as being anticipated by Cosman et al (1984)? Are claims 74, 76, 82, and 84 properly rejected under 35 U.S.C §103 as being unpatentable over Cosman et al (1984) in combination with Cosman ('597)? Are claims 54, 55, 74 properly rejected under 35 U.S.C §103 as being unpatentable over Cosman et al (1984) in combination with Makower et al? Are claims 89-94 properly rejected under 35 U.S.C §103 as being unpatentable over Makower et al in combination with Cosman et al (1984)?

(7) Grouping of Claims

None of the claims rise and fall together besides those specifically stated herein. Claims 48, 50, 53, 74, 75, 78, 79, 82, 83, and 86 rise and fall together. Claims 77, 80, 81, 85, 87, and 88 rise and fall together.

(8) Argument

Applicants' remarks are proceeded by the Examiner's comments from the final office action in small, bold face type.

Claims 48, 50, 53, 74, 75, 77-83, and 85-88 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Cosman et al (1984).

Wherein the interior of the electrode is the conductive material and the surface of the electrode is the surface material. Any interstitial fluid present will provide the composite temperature readings referred to. See Figures 2 and 3 and page 946, column 2 to page 948, column 2.

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> **Applicant appears to be arguing that Cosman et al (1984) does not read on the amended claims because there is no disclosure in Cosman et al (1984) to employ the device in an environment as discussed by applicant. This argument must fail for several reasons. Firstly, since the structure taught by Cosman et al (1984) reads on the claimed device, the device of Cosman et al (1984) would inherently behave as applicants claimed structure when put in the same environment. Secondly, the apparatus claims at bar do not recite the environment in which the device is to be used, and in fact cannot properly recite such environment, since this must include the patient's body structures (for example those tissues which would confine any irrigant in the operative space). And thirdly, the device of Cosman et al is intended to be used on the brain and spinal column, which are surrounded by cerebrospinal fluid, which would read on the fluid medium claimed.**

Contrary to the Examiner's assertion, Cosman et al. (1984) does not describe or suggest a structure that reads on the claimed device. Cosman et al. (1984) does not describe or suggest a sensor positioned within the thermally conductive material to detect a thermal energy from the selected site and from an adjacent fluid medium, as claimed in independent claims 74 and 82. The Examiner is apparently equating interstitial fluid to the claimed adjacent fluid medium. However, as illustrated in Fig. 3 and discussed in the second full paragraph of page 11 of the applicant's specification, the adjacent fluid medium 30 is extrastitial to the collagen containing tissue being treated, i.e., not within the tissue of the selected site itself.

Cosman et al. (1984) is silent as to the position of the sensor other than specifying that the sensor is built into the small, sharpened tip of the device, and that in use the tip is located in the spinal cord. In fact, Fig. 3 of Cosman et al. (1984) shows the entire tip of the device located within tissue being treated. Thus, Cosman's sensor is positioned to only detect thermal energy from the selected site, not from an adjacent fluid medium.

Furthermore, there is nothing in Cosman et al. (1984) that teaches one skilled in the art to position the sensor in the tip such that the sensor can detect thermal energy from both a selected site and adjacent fluid. As such, the Examiner is apparently relying on an inherency argument, i.e., that in use it would be possible to position the tip of Cosman et al. (1984) at a selected site such that the sensor of Cosman et al. (1984) would detect thermal energy from the selected site and the adjacent fluid medium. However, such a possibility is not a proper basis for inherency.

> To establish inherency, the extrinsic evidence "must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill."... "Inherency,

> however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient." In re Robertson, 169 F.3d 743 (Fed. Cir. 1999).

Cosman et al. (1984) does not describe the subject matter of independent claims 74 and 82 "with sufficient clarity and detail to establish that the subject matter existed and that its existence was recognized by persons of ordinary skill in the filed of the invention." ATD Corp. v. Lydall, Inc., 159 F.3d 534.

Furthermore, the position of the sensor is critical to the applicants' invention. If the sensor is not positioned correctly, the sensor will not detect thermal energy from both the selected site and the adjacent fluid medium. As discussed in line 19 of page 17 to line 13 of page 18 and with reference to Figs. 9a-9d of the present application, the position of the sensor determines whether the sensor detects thermal energy from both the selected site and adjacent fluid medium.

Therefore, claims 74 and 82 and their dependent claims are patentable over Cosman et al. (1984) for at least the reasons discussed above.

In the applicants' response to final office action, filed November 17, 2003, applicants requested that the examiner provide support for the examiner's position that the brain and spinal column "are surrounded by cerebrospinal fluid, which would read on the fluid medium claimed." In the Advisory Action dated December 17, 2003, the examiner stated that "an affidavit from applicants stating that no fluid exists in the cerebrosprinal spaces of living beings would be needed to bolster the mere assertion that CSF does not exist." The applicants did not assert that cerebrospinal fluid (CSF) does not exist. The applicants point was not whether the brain and spinal column are surrounded by cerebrospinal fluid, but whether any such "fluid read on the fluid medium claimed", i.e., a fluid medium adjacent a selected site and from which a sensor was positioned to detect thermal energy.

Furthermore, regarding dependent claims 77, 80, 81, 85, 87, and 88 Cosman et al. (1984) does not describe the claimed conductive material at a position proximal to the sensor. Cosman et al. (1984) is silent as to the relative position of the sensor and any conductive material other than specifying that the sensor is built into the small, sharpened tip of the device.

> **Claims 74, 76, 82, and 84 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cosman et al. (1984) in combination with Cosman ('597). Cosman et al. (1984) provide the teachings set forth above. Cosman ('597) teach forming electrodes of stainless steel. It would have been obvious to the artisan of ordinary skill to form the electrode of Cosman et al. (194) of stainless steel since this is a well known electrode material, and useful for forming thermocouple junctions, thus producing a device such as claimed.**

Cosman '597 does not overcome the deficiencies in Cosman et al. (1984) discussed above. In particular, Cosman '597 does not describe or suggest the claimed sensor positioned within thermally conductive material to detect thermal energy from a selected site and from an adjacent fluid medium.

> **Claims 54, 55 and 74 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cosman et al. (1984) in combination with Makower et al. Cosman et al. (1984) provide the teachings set forth above. Makower et al. teach the equivalence of microwave, radio frequency, and resistive heating in energy delivery devices. It would have been obvious to the artisan of ordinary skill to employ a resistive or microwave tissue heater in the device of Cosman et al. (1984), since these are well known equivalents in the art, as thought by Makower et al. and provide no unexpected result, thus producing a device such as claimed.**

Makower et al. does not overcome the deficiencies in Cosman et al. (1984) discussed above. In particular, Makower et al. does not describe or suggest the claimed sensor positioned within thermally conductive material to detect thermal energy from a selected site and from an adjacent fluid medium.

> **Claims 89-94 are rejected under 35 U.S.C. 103(a) as being unpatentable over Makower et al. in combination with Cosman et al (1984). Makower et al. teach a method such as claimed except for the specific recitation of moving and returning the applicator and the sensor completely enclosed by the thermally conductive material of the probe. Cosman et al (1984) teach a thermistor surrounded by conductive material. It would have been obvious to the artisan of ordinary skill to employ the energy applicator of Cosman et al (1984) in the method of Makower et al, since Makower et al teach no particular form for the high frequency applicator, and to re-insert the probe for subsequent treatment as taught by Makower et al page 20, thus sensing the combined temperature of the tissue and the fluids either exogenous or endogenous, therein, thus producing a method such as claimed.**

As discussed above, neither Makower et al. nor Cosman (1984) describes or suggests the claimed sensor positioned within thermally conductive material to detect thermal energy from a selected site and from an adjacent fluid medium. Therefore, claim 89 and its dependent claims

are patentable over Makower et al. in combination with Cosman et al. (1984) for at least the reasons discussed above.

Regarding dependent claim 90, neither Makower et al. nor Cosman et al. (1984) describe or suggest "moving the energy delivery device back toward the portion of collagen containing tissue at the selected site, after moving away, and sensing an elevated composite temperature due to the increased thermal energy in the [adjacent] fluid medium," as claimed. In particular, contrary to the Examiner's assertion, page 20 of Makower et al. does not describe reinserting a probe for subsequent treatment, but rather describes removing one device and inserting a different device for subsequent treatment. Furthermore, neither Makower et al. nor Cosman et al. (1984) describe sensing the temperature of adjacent fluid medium, let alone a composite temperature.

Regarding dependent claim 93, neither Makower et al. nor Cosman et al. (1984) describe or suggest that "producing a thermal feedback signal comprises sensing an elevated composite temperature due to the increased thermal energy in the [adjacent] fluid medium," as discussed above, or that "delivering an adjusted level of energy comprises delivering a lower level of energy to reduce stray contractions caused by increased thermal energy in the [adjacent] fluid medium," as claimed. Makower et al. and Cosman et al. (1984) do not address adjusting the level of energy due to an effect increased thermal energy in adjacent fluid medium has on the tissue being treated.

A check for the brief fee and an extension of time fee is enclosed. Please apply any other charges or credits to Deposit Account No. 06-1050.

Respectfully submitted,

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Appendix of Claims

48. The apparatus of claim 74, further comprising:

a thermal insulator positioned at least partially around an exterior surface of the energy delivery device.

50. The apparatus of claim 74, further comprising:

a thermally conductive material coupling the sensor to an exterior surface of the distal portion.

53. The apparatus of claim 74, wherein the energy delivery device is an RF energy delivery device coupled to an RF energy source.

54. The apparatus of claim 74, wherein the energy delivery device is a resistive heating element coupled to a resistive heating source.

55. The apparatus of claim 74, wherein the energy delivery device is a microwave probe coupled to a microwave source.

74. An apparatus comprising:

an energy delivery device including a proximal portion and a distal portion, the energy delivery device being configured to deliver sufficient energy to a selected site to effect a contraction in at least a portion of collagen containing tissue at the selected site, the distal portion including a thermally conductive material; and

a sensor completely enclosed by the thermally conductive material, and positioned within the thermally conductive material to detect a thermal energy from the selected site and from an adjacent fluid medium, the sensor producing a thermal feedback signal which represents a composite of the thermal energy detected from the selected site of the collagen containing tissue and from the fluid medium, the energy delivery device including circuitry for supplying the thermal feedback signal to a feedback control system for adjusting a level of energy delivered by

the energy delivery device to at least the portion of the selected site of the collagen containing tissue.

75. The apparatus of claim 74, further comprising a surface material forming at least part of an exterior surface of the energy delivery device and covering at least part of the thermally conductive material.

76. The apparatus of claim 75, wherein the surface material comprises stainless steel.

77. The apparatus of claim 74, wherein the thermally conductive material that surrounds the sensor extends from a distal tip of the energy delivery device to a position proximal to the sensor.

78. The apparatus of claim 74, wherein the circuitry for supplying the thermal feedback signal to the feedback control system comprises a conductor.

79. The apparatus of claim 74, wherein the thermally conductive material that surrounds the sensor forms at least part of an exterior surface of the energy delivery device.

80. The apparatus of claim 79, wherein the part of the exterior surface formed by the thermally conductive material extends from a distal tip of the energy delivery device to a position proximal to the sensor.

81. The apparatus of claim 79, wherein the part of the exterior surface formed by the thermally conductive material includes substantially all exterior surface of the energy delivery device from a distal tip of the energy delivery device to a position proximal to the sensor.

82. An apparatus comprising:

an energy delivery device including a proximal portion and a distal portion, the energy delivery device being configured to deliver sufficient energy to a selected site to effect a

contraction in at least a portion of collagen containing tissue at the selected site, the distal portion including a thermally conductive material;

a sensor completely enclosed by the thermally conductive material, the sensor being positioned within the thermally conductive material to detect a thermal energy from the selected site and from an adjacent fluid medium, the sensor producing a thermal feedback signal which represents a composite of the thermal energy detected from the selected site of the collagen containing tissue and from the fluid medium; and

a feedback control system coupled to the sensor and configured to receive the thermal feedback signal and adjust a level of energy delivered by the energy delivery device to at least the portion of the selected site of the collagen containing tissue.

83. The apparatus of claim 82, further comprising a surface material forming at least part of an exterior surface of the energy delivery device and covering at least part of the thermally conductive material.

84. The apparatus of claim 83, wherein the surface material comprises stainless steel.

85. The apparatus of claim 82, wherein the thermally conductive material that surrounds the sensor extends from a distal tip of the energy delivery device to a position proximal to the sensor.

86. The apparatus of claim 82, wherein the thermally conductive material that surrounds the sensor forms at least part of an exterior surface of the energy delivery device.

87. The apparatus of claim 86, wherein the part of the exterior surface formed by the thermally conductive material extends from a distal tip of the energy delivery device to a position proximal to the sensor.

88. The apparatus of claim 86, wherein the part of the exterior surface formed by the thermally conductive material includes substantially all exterior surface of the energy delivery device from a distal tip of the energy delivery device to a position proximal to the sensor.

89. A method of delivering energy, the method comprising:

providing an energy delivery device including a distal portion having a thermally conductive material and a sensor completely enclosed by the thermally conductive material, the sensor being positioned within the thermally conductive material to detect a thermal energy from the selected site and from an adjacent fluid medium;

delivering sufficient energy with the distal portion of the energy delivery device to a selected site to effect a contraction in at least a portion of collagen containing tissue at the selected site;

producing a thermal feedback signal which represents a composite of the thermal energy detected from the selected site of the collagen containing tissue and from the adjacent fluid medium with the sensor; and

adjusting a level of energy delivered by the energy delivery device to at least the portion of the selected site based on the thermal feedback signal.

90. The method of claim 89, wherein delivering sufficient energy to the selected site to effect a contraction in at least a portion of collagen containing tissue at the selected site causes fluid medium in a vicinity of the portion of collagen containing tissue to increase in thermal energy, and the method further comprises:

moving the energy delivery device away from the portion of collagen containing tissue at the selected site after delivering sufficient energy; and

moving the energy delivery device back toward the portion of collagen containing tissue at the selected site, after moving away, and sensing an elevated composite temperature due to the increased thermal energy in the fluid medium.

91. The method of claim 90, wherein at least part of the increased thermal energy in the fluid medium is dispersed through the fluid medium.

92. The method of claim 90, wherein delivering an adjusted level of energy comprises delivering a lower level of energy to reduce overheating of the previously heated portion of collagen containing tissue, the lower level of energy being based on the elevated composite temperature that was sensed.

93. The method of claim 89, wherein:

delivering sufficient energy to the selected site to effect a contraction in at least a portion of collagen containing tissue at the selected site causes fluid medium in a vicinity of the portion of collagen containing tissue to increase in thermal energy,

producing a thermal feedback signal comprises sensing an elevated composite temperature due to the increased thermal energy in the fluid medium, and

delivering an adjusted level of energy comprises delivering a lower level of energy to reduce stray contractions caused by increased thermal energy in the fluid medium.

94. The method of claim 89, wherein thermal energy is conducted through the thermally conductive material to the sensor.